AUG 1 8 2000

K001589

510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Dynamic Cooling Device, which is substantially equivalent to previously marketed devices intended for cooling of the skin and reduction of pain during laser treatment (K951033) and for protecting the dermis from thermal injury, which reduces possible side effects such as scabbing, scarring, and hyperpigmentation (K972347) and allows for the utilization of higher laser fluences for laser treatment.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Joan M. Clifford
Date prepared:	May 19, 2000
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Trade Name:	Candela Dynamic Cooling Device
Common Name:	Skin Refrigerant
Predicate Devices:	Candela Dynamic Cooling Device cleared under 510(k) K951033 and the Epidermal Chiller tip accessory to Coherent, Inc.'s Versapulse Aesthetic Surgical Laser cleared under 510(k) K972347

Description:

Candela's Dynamic Cooling Device consists of 1) a source of skin refrigerant fluid (HFC 134a), 2) an electronically controlled solenoid delivery valve, and 3) electronic timing circuitry. The Dynamic Cooling Device is connected in line with a laser's triggerswitch system so that activation of the triggerswitch controls the delivery of a pulsed spray of HFC 134a just prior to the delivery of a laser pulse. The pulsed spray of skin refrigerant cools the skin as it evaporates. Thermal injury to non-vascular structures is minimized and pain associated with the laser treatment is reduced.

The intended use of the Candela Dynamic Cooling Device is to minimize injury to the skin structures during laser therapy of vascular lesions and hair removal, to reduce pain associated with laser treatment, to allow for use of higher laser fluences and to reduce potential side effects of laser treatments, such as hair removal and vascular lesions.

Summary of Substantial Equivalence:

The Candela Dynamic Cooling Device for the use of higher laser fluences and reduction of potential side effects of laser treatments is substantially equivalent to the Candela Dynamic Cooling Device which has been previously cleared for cooling of the skin prior to and reduction of pain during laser treatment. (K951033). Operating principles materials, design, construction, methods of assembly and other intended uses are the same as those for the predicate device. With respect to indications for use, Candela's Dynamic Cooling device is also substantially equivalent to Coherent Inc.'s Epidermal Chiller tip accessory (K972347).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

Ms. Joan M. Clifford
Clinical Research Manager
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K001589
Trade Name: Candela Dynamic Cooling Device
Regulatory Class: II
Product Code: GEX
Dated: May 19, 2000
Received: May 23, 2000

Dear Ms. Clifford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001589

Device Name: Candela Dynamic Cooling Device

Indications for Use:

The intended use of the Candela Dynamic Cooling Device is:

(1) cooling of the skin prior to laser treatment

(2) reduction of pain during laser treatment

(3) allows for use of higher laser fluences for laser treatments, such as for hair removal and vascular lesions

(4) reduces potential side effects of laser treatments, such as for hair removal and vascular lesions

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional format 1-2-96)

Donna R. Lochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001589